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PATENT  
0690-0110P

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: Wolfgang M. FRANZ et al. Conf.: 2640  
Appl. No.: 09/068,751 Group: 1635  
Filed: November 2, 1998 Examiner: ZARA, J.J.  
For: GENE-THERAPEUTIC NUCLEIC ACID CONSTRUCT,  
PRODUCTION OF SAME AND USE OF SAME IN THE  
TREATMENT OF HEART DISEASE

INFORMATION DISCLOSURE STATEMENT  
(SUBMISSION AFTER FILING OF AN APPLICATION  
BUT BEFORE FINAL REJECTION OR NOTICE OF ALLOWANCE  
OR CONCURRENTLY WITH A RULE 1.114 RCE APPLICATION)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

May 17, 2004

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-1449(s), attached hereto.

II. COPIES (check at least one box)

- a.  This application was filed before June 30, 2003. Accordingly, submitted herewith is a legible copy of (i) each U.S. and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.
- b.  This application was filed on or after June 30, 2003. Accordingly, copies of cited U.S. patents and patent application publications therefore are not included. Copies of foreign

patent documents and non-patent literature are included.

- c.  Some or all of the documents listed on the PTO-1449 are not enclosed because they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned.

**III. CONCISE EXPLANATION OF THE RELEVANCE**  
(check at least one box)

- a.  **DOCUMENTS IN THE ENGLISH LANGUAGE**

The patents, publications, or other information listed on the attached PTO 1449 are in the English language and therefore, do not require a statement of relevancy.

- b.  **DOCUMENTS NOT IN THE ENGLISH LANGUAGE**

A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

- c.  **ENGLISH LANGUAGE SEARCH REPORT**

An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).

- d.  **OTHER**

The following additional information is provided for the Examiner's consideration.

*Additional references have been cited in co-pending application 10/049,825 but appear to be directed to aspects of that invention other than cardiomyocyte specific expression or gene-transfer. The Examiner is urged to review the file of that application to make her own determination of relevance of such additional references.*

FEES

IV.  THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b) :  
(check one box)

- a.  within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required. (*This section is not to be used with RCE's.*)
- b.  within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.
- c.  concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.
- d.  before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required.  
In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

V.  THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c) :  
(check one box)

before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

- a.  No statement; therefore, a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).  
or
- b.  See the statement below. No fee is required.

VI. STATEMENT UNDER 37 C.F.R. § 1.97(e) (check only one box)

The undersigned hereby states that

- a.  each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than 30 days prior to the filing of this IDS; or
- b.  each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- c.  no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.
- d.  Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VII. PAYMENT OF FEES (check one box)

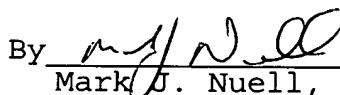
- A check in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p) is enclosed for the above-identified fee.
- Please charge Deposit Account No. 02-2448 in the amount required by 37 C.F.R. § 1.17(p) for the above-indicated fee. A triplicate copy of this paper is attached.
- No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By   
Mark J. Nuell, #36,623

DRN/mua  
0690-0110P

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- Attachment(s):  PTO-1449  
 Documents  
 Foreign Search Report  
 Fee  
 Other:

(Rev. 05/14/2004)

| Form PTO-1449<br><br>OIPC INFORMATION DISCLOSURE CITATION<br>IN AN APPLICATION<br><br>(Use several sheets if necessary)<br><br>MAY 17 2004<br>PATENT TRADEMARK OFFICE   |   |                 |            | ATTY. DOCKET NO.<br>0690-0110P        | APPLICATION NO.<br>09/068,751 |           |                            |             |
|---|---|-----------------|------------|---------------------------------------|-------------------------------|-----------|----------------------------|-------------|
|   |   |                 |            | APPLICANT<br>Wolfgang M. FRANZ et al. |                               |           |                            |             |
|   |   |                 |            | FILING DATE<br>November 2, 1998       | GROUP<br>1635                 |           |                            |             |
| <b>U.S. PATENT DOCUMENTS</b>  |   |                 |            |                                       |                               |           |                            |             |
|   | DOCUMENT NUMBER   | KIND            | DATE       | NAME                                  | CLASS                         | SUB CLASS | FILING DATE IF APPROPRIATE |             |
|   | US 6,080,569  |                 | 2000-06-27 | Graham et al.                         |                               |           |                            |             |
|   | US 5,602,301  |                 | 1997-02-11 | Field                                 |                               |           |                            |             |
|   | US  |                 |            |                                       |                               |           |                            |             |
| <b>FOREIGN PATENT DOCUMENTS</b>   |   |                 |            |                                       |                               |           |                            |             |
|   | Office  | DOCUMENT NUMBER | KIND       | DATE                                  | COUNTRY                       | CLASS     | SUB CLASS                  | TRANSLATION |
|   | WO  | 99/39571        | A1         | 1999-08-12                            | PCT                           |           |                            | YES      NO |
|   | WO  | 96/16163        | A2         | 1996-05-30                            | PCT                           |           |                            | ABS         |
|   | WO  | 97/17937        | A2         | 1997-05-22                            | PCT                           |           |                            | ABS         |
| <b>OTHER DOCUMENTS</b> (Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.) |   |                 |            |                                       |                               |           |                            |             |
|   | M.G. KLUG et al., J. Clin. Invest., Vol. 98, No. 1, July 1996, pp. 216-224.         |                 |            |                                       |                               |           |                            |             |
|   | A.M. WOBUS et al., J. Mol. Cell Cardiol. Vol. 29, 1997, pp. 1525-1539.              |                 |            |                                       |                               |           |                            |             |
|   | W.M. FRANZ et al., Abstract of J. Mol. Cell Cardiol. Vol. 29, No. 5, 1997, A125.    |                 |            |                                       |                               |           |                            |             |
|   | D. ZINK et al., Gene Therapy and Molecular Biology, Vol. 6, January 2001, pp. 1-24. |                 |            |                                       |                               |           |                            |             |
|   | N. MILLER et al., Human Gene Therapy, Vol. 8, May 1, 1997, pp. 803-815.             |                 |            |                                       |                               |           |                            |             |
|   | I.M. VERMA et al., Nature, Vol. 389, September 18, 1997, pp. 239-242.               |                 |            |                                       |                               |           |                            |             |
|   | N. MILLER et al., FASEB Journal, Vol. 9, February 1995, pp. 190-199.                |                 |            |                                       |                               |           |                            |             |
|   | S.C. MAKRIDES, Protein Expression and Purification, Vol. 17, 1999, pp. 183-202.     |                 |            |                                       |                               |           |                            |             |
|   | D.W. RUSSELL et al., Nature Genetics, Vol. 18, April 1998, pp. 325-330.             |                 |            |                                       |                               |           |                            |             |
|   | P.D. ROBBINS et al., Pharmacol. Ther., Vol. 80, No. 1, 1998, pp. 35-47.             |                 |            |                                       |                               |           |                            |             |
| EXAMINER  |   |                 |            | DATE CONSIDERED                       |                               |           |                            |             |
| EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.   |   |                 |            |                                       |                               |           |                            |             |

Form PTO-1449

ATTY. DOCKET NO.  
0690-0110PAPPLICATION NO.  
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## APPLICANT

Wolfgang M. FRANZ et al.

## FILING DATE

November 2, 1998

## GROUP

1635

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(Use several sheets if necessary)

MAY 17 2004

U.S. PATENT DOCUMENTS

| EXAMINER'S INITIAL | DOCUMENT NUMBER | KIND | DATE | NAME | CLASS | SUB CLASS | FILING DATE IF APPROPRIATE |
|--------------------|-----------------|------|------|------|-------|-----------|----------------------------|
|                    | US              |      |      |      |       |           |                            |
|                    | US              |      |      |      |       |           |                            |
|                    | US              |      |      |      |       |           |                            |
|                    | US              |      |      |      |       |           |                            |
|                    | US              |      |      |      |       |           |                            |

## FOREIGN PATENT DOCUMENTS

| Office | DOCUMENT NUMBER | Kind | DATE | COUNTRY | CLASS | SUB CLASS | TRANSLATION |    |
|--------|-----------------|------|------|---------|-------|-----------|-------------|----|
|        |                 |      |      |         |       |           | YES         | NO |
|        |                 |      |      |         |       |           |             |    |
|        |                 |      |      |         |       |           |             |    |
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|        |                 |      |      |         |       |           |             |    |
|        |                 |      |      |         |       |           |             |    |

**OTHER DOCUMENTS** (Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.)

M.P. DEONARAIN, Exp. Opin. Ther. Patents, Vol. 8, No. 1, 1998, pp. 53-69.

C.A. MACK et al., J. of Thoracic and Cardiovascular Surgery, Vol. 115, No. 1, January 1998, pp. 168-177.

F. GRISCELLI et al., Human Gene Therapy, Vol. 9, September 1, 1998, pp. 1919-1928.

M. MULLER et al., FASEB Journal, Vol. 14, December 2000, pp. 2540-2548.

R.C. BOUCHER, Journal of Clinical Investigation, Vol. 103, No. 4, February 1999, pp. 441-445.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.